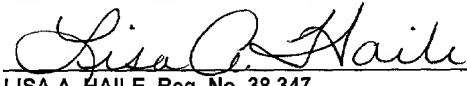


US

NATIONAL CHAPTER - US

Annex US.II, page 1

FORM PTO-1390 (REV 11-2000)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER SHIM1120	
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371				U.S. APPLICATION NO. (if known, see 37 CFR 1.5)	
				09/830019	
INTERNATIONAL APPLICATION NO. PCT/JP99/05789		INTERNATIONAL FILING DATE 20 October 1999		PRIORITY DATE CLAIMED 21 October 1998	
TITLE OF INVENTION VACCINE PREPARATIONS CONTAINING ATTENUATED TOXIN					
APPLICANT(S) FOR DO/EO/US Chikara AIZAWA, Yujiro SUZUKI, Taka-aki SATO, Koji WATANABE, Nobuaki HATTORI, Yoshitake TANAKA & Satoshi OMURA					
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:					
<ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 USC 371. 2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing 35 USC 371. 3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 USC 371(f)). The submission must include items (5), (6), (9), and (21) indicated below. 4. <input type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (Article 31). 5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input checked="" type="checkbox"/> An English language translation of the International Application as filed (35 USC 371(c)(2)) <ol style="list-style-type: none"> a. <input checked="" type="checkbox"/> is attached hereto b. <input type="checkbox"/> has been previously submitted under 35 USC 154(d)(4) 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 USC 371(c)(3)). 9. <input checked="" type="checkbox"/> An unsigned oath or declaration of the inventor(s) (35 USC 371(c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 USC 371(c)(5)). <p>Items 11. to 16. below concern other document(s) or information included:</p> <ol style="list-style-type: none"> 11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input checked="" type="checkbox"/> A FIRST preliminary amendment. 14. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A change of power of attorney and/or address letter. 17. <input type="checkbox"/> A computer-readable form of sequence listing in accordance with PCT Rule 13 and 35 USC 1821-1825 18. <input type="checkbox"/> A second copy of the published International Application under 35 USC 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the International Application under 35 USC 154(d)(4). 20. <input checked="" type="checkbox"/> Other items or information: Express Mail Certification 					

U.S. APPLICATION NO. (If known, see 37 CFR 1.6) 09/830019		INTERNATIONAL APPLICATION NO PCT/JP99/05789		ATTORNEY'S DOCKET NO SHIM1120	
21. The following fees are submitted:				CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5)): Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO.. \$1,000.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by EPO or JPO \$ 860.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$ 710.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4). \$ 690.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4). \$ 100.00 ENTER APPROPRIATE BASIC FEE AMOUNT =				\$ 860.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than 20 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	12 - 20 =		x \$ 18.00	\$	
Independent Claims	1 - 3 =		x \$ 80.00	\$	
Multiple dependent claim(s) (if applicable)			+ \$270.00	\$	
TOTAL OF ABOVE CALCULATIONS =				\$ 860.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$	
SUBTOTAL =				\$ 860.00	
Processing fee of \$130. for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +				\$	
TOTAL NATIONAL FEE =				\$ 860.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$	
TOTAL FEES ENCLOSED =				\$ 860.00	
				Amount to be refunded:	\$
				charged:	\$
<p>a. <input checked="" type="checkbox"/> A check in the amount of \$ <u>860.00</u> to cover the above fees is enclosed.</p> <p>b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>50-1355</u>. A duplicate copy of this sheet is enclosed.</p> <p>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.</p>					
SEND ALL CORRESPONDENCE TO: GRAY CARY WARE & FREIDENRICH 4365 Executive Drive, Suite 1600 San Diego, California 92121			 LISA A. HAILE, Reg. No. 38,347 4/19/01 Date		
PHONE: 858/677-1456 - FAX: 858/677-1465					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
 AIZAWA et al) Group No.: Unknown
)
 Serial No.: Unknown) Examiner: Unknown
)
 Filed: Herewith) Docket No. SHIM1120
)
For: VACCINE PREPARATIONS CONTAINING ATTENUATED TOXIN

BOX PCT
 Assistant Commissioner for Patents
 Washington, D.C. 20231

Sir:

PRELIMINARY AMENDMENT

In advance of the first examination in this case, Applicants request amendment of the subject application, as follows:

IN THE CLAIMS

Please amend the claims as follows:

4. (Amended) The adjuvant of [any of] claim[s] 1 [to 3], wherein said toxin is a bacterial toxin.
8. (Amended) A vaccine preparation comprising the adjuvant of [any one of] claim[s] 1 [to 7] and one or more vaccine antigens.

REMARKS

Claims 4 and 8 have been amended. Claims 1-12 remain in the application.

This Preliminary Amendment is submitted in advance of the first examination of the subject application. No new matter has been entered.

Respectfully submitted,

Lisa A. Haile

LISA A. HAILE
 Reg. No. 38,347

Date:

4/19/01

GRAY CARY WARE & FREIDENRICH
 4365 Executive Drive, Suite 1600
 San Diego, CA 92121-2189

Telephone: (858) 677-1456 Fax: (858) 677-1465